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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,928	02/10/2004	Wing K. Cheung	JJPR-0048(ORT-1223)	1406

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,928	CHEUNG ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-33 and 35-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-33 and 35-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20060123*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 23, 2006 has been entered.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

3. Claims 1, 2, 7, 12, 14-16, 22, 23, 28, 33, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Woog et al (U.S. Patent No. 5,503,827). Woog et al teach an aqueous pharmaceutical preparation comprising erythropoietin, a pH buffering agent (i.e. sodium phosphate monobasic/sodium phosphate dibasic), Tween 20 (i.e. polysorbate 20), a stabilizing amount of glycine, and sodium chloride (i.e. a tonicity agent). Tween 20 concentration is about 0.1 g/l, and glycine concentration is about 1.5 g/l. The composition does not contain any urea, human blood product such as serum albumin, or calcium chloride. See Example 1, third column of the table, where the dash in the row "calcium chloride x $2H_2O$" is interpreted as meaning that no calcium chloride is present. See also column 9, lines 5-12, for the function of glycine in the preparation. With respect to instant claims 15, 16, 36, and 37, a quantity per dose is a method of use limitation, i.e. is an extrinsic rather than an intrinsic variable, and does not impart patentability to a product claim which is otherwise anticipated by the prior art. In any event, Woog et al disclose erythropoietin doses of preferably 2000 and 10,000 U (see column 8, lines 9-13).

4. Claims 3-6, 8-11, 24-27, and 29-32 are rejected under 35 U.S.C. 103(a) as being obvious over Woog et al (U.S. Patent No. 5,503,827). Application of Woog et al is the same as in the above rejection of claims 1, 2, 7, 12, 14-16, 22, 23, 28, 33, and 35-37. Woog et al teach the presence of a sodium phosphate monobasic/sodium phosphate dibasic buffer, and teach in

general buffer concentrations of about 1 - 100 mmol/l and pharmaceutical preparation pHs of about 4.5 to 7.5 (see column 8, lines 25-37), but do not teach Applicants' claimed buffer concentration and pharmaceutical preparation pH. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal buffer concentrations and pharmaceutical preparation pHs within the disclosed ranges of Woog et al because concentration and pH are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts, and which Woog et al teach must be chosen for pharmaceutical use.

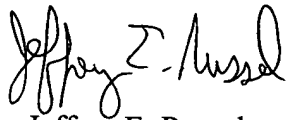
5. Claims 17-21 and 38-42 are rejected under 35 U.S.C. 103(a) as being obvious over Woog et al (U.S. Patent No. 5,503,827) as applied against claims 1, 2, 7, 12, 14-16, 22, 23, 28, 33, and 35-37 above, and further in view of Woog et al (U.S. Patent No. 4,992,419). In Example 1, third column of the table, Woog et al '827 teaches an erythropoietin composition comprising Tween 20 rather than Tween 80. Woog et al '827 do not teach the function of the Tween 20 in the composition. Woog et al '419 teaches erythropoietin compositions in which a non-ionic wetting agent, preferably Tween 20 or 80, is included to prevent adhesion of erythropoietin onto ampoule walls and syringes. See column 2, line 64 - column 3, line 9. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute Tween 80 for Tween 20 in the erythropoietin composition of Woog et al '827 because Woog et al '419 teach them to be functionally equivalent in prevent adhesion of erythropoietin onto apparatus walls, and because the substitution of one known functional equivalent for another is prima facie obvious. Woog et al '827 does not teach a pH for its composition, although in general Woog et al '827 teaches pHs of about 4.5 to 7.5 (see column 8, lines 25-37). It would have been obvious

to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal pharmaceutical preparation pHs within the disclosed ranges of Woog et al '827 for the composition of Woog et al '827 as modified above by Woog et al '419 because pH is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts, and which Woog et al '827 teaches must be chosen for pharmaceutical use.

6. Woog et al (U.S. Patent No. 5,503,827), applied above, is an English-language equivalent of European Patent Application 528,313 cited in the Information Disclosure Statement filed January 23, 2006.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel
May 1, 2006